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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,920	03/22/2001	Sherman Fong	P1192-2	6172

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Offic Action Summary	Application No. 09/816,920	Applicant(s) FONG ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to nucleic acid, vector, host cell and method of making, classified in class 435, subclass 69.1.

II. Claims 15-21, 27a, 28-31a drawn to isolated Bolekine polypeptide and pharmaceutical composition and kit, classified in class 530, subclass 350.

III. Claims 22-24, 27d-31d, drawn to the antibody, the pharmaceutical composition and kit, classified in class 530, subclass 387.9.

IV. Claims 25, 27b, 28-31b drawn to Bolekine agonists, the pharmaceutical composition and kit, classified in class dependent on agonist.

V. Claims 26, 27c-31c drawn to Bolekine antagonists, the pharmaceutical composition and kit classified in class dependent on antagonist.

VI. Claims 32, 33 drawn to a method for treating a disorder comprising administering to a mammal a Bolekine polypeptide, classified in class 512, subclass 2.

VII. Claim 32, 33 drawn to a method for treating a disorder comprising administering to a mammal an agonist, classified in class dependent on agonist.

VIII. Claims 32, 33, drawn to a method for treating a disorder comprising administering to a mammal an antagonist, classified in class dependent on antagonist.

IX. Claims 32, 33, drawn to a method for treating a disorder comprising administering to a mammal an antibody, classified in class 424, subclass 130.1.

X. Claims 34, 36, drawn to method determining presence of polypeptide in a sample comprising exposing a sample to an antibody, classified in class 435, subclass 7.1.

XI. Claim 35, 38, 39 drawn to a method for diagnosing a disease comprising detecting the level of gene expression in a sample and a method for identifying a compound that inhibits gene expression comprising contacting cells with a compound to determine gene expression, classified in class 435, subclass 6.

XII. Claims 37, drawn to a method for identifying a compound that inhibits polypeptide activity comprising contacting cells with a polypeptide and candidate compound, classified in class 435, subclass 7.8.

XIII. Claim 40, drawn to a method for identifying a compound that mimics polypeptide activity comprising contacting cells with a candidate compound, classified in class 435, subclass 7.8.

XIV. Claim 41, drawn to a method of stimulating proliferation of T-lymphocytes comprising contacting T-lymphocytes with a polypeptide or an agonist, classified in class 435, subclass 7.8.

XV. Claim 42, drawn to a method of inhibiting proliferation of T-lymphocytes comprising contacting T-lymphocytes with an antagonist classified in

class 435 , subclass 7.8.

XVI. Claims 43, 44, drawn to a method of enhancing the infiltration of inflammatory cells of a mammal comprising administering an effective amount of a Bolekine polypeptide, classified in class 512, subclass 2.

XVII. Claims 43, 44, drawn to a method of enhancing the infiltration of inflammatory cells of a mammal comprising administering an agonist, classified in class dependent on agonist.

XVIII. Claims 45, 46, drawn to a method of inducing the differentiation of pluripotent cells into neuronal cells in a mammal comprising administering an effective amount of a Bolekine polypeptide, classified in class 514, subclass 2.

XVIX. Claims 45, 46, drawn to a method of inducing the differentiation of pluripotent cells into neuronal cells in a mammal comprising administering an effective amount of an antagonist, class dependent on antagonist.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-V are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I,

such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). The antibody of Group III can be used to obtain the protein of Group II or the recombinantly expressed protein of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Groups IV is drawn to an agonists. Group V is drawn to an antagonists. Both of these Groups are different from one another and Groups I-III because the Groups IV and V can encompass nucleic acids, proteins, antibodies and/or various chemicals structures.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups VI-XVIX are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. A search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I/XI and II/VI,XII,XIV,XVI,XVIII and III/IX,X and IV/VII,XIV,XVII and V/VIII,XV,XVIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in processes to make proteins. Group II can be used in processes to make antibodies, the product of Group III can be used in immunoassays and the products of Group IV and Group V (depending on the type of agonist and antagonist) can be used in gene therapy, in nucleic acid hybridization assays or the processes cited above.

Inventions I/VI-X,XII-XVIX and II/VII-XI,XIII,XV,XVII,XVIX and III/VI-VIII,XI-XVIX and IV/VI,VIII-XIII,XV,XVI,XVIII,XVIX and V/VI,VII,VIX-XIV,XVI-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Claim 33 is generic to a plurality of disclosed patentably distinct species comprising an immune related disorder. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
June 5, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER